

### **REMARKS**

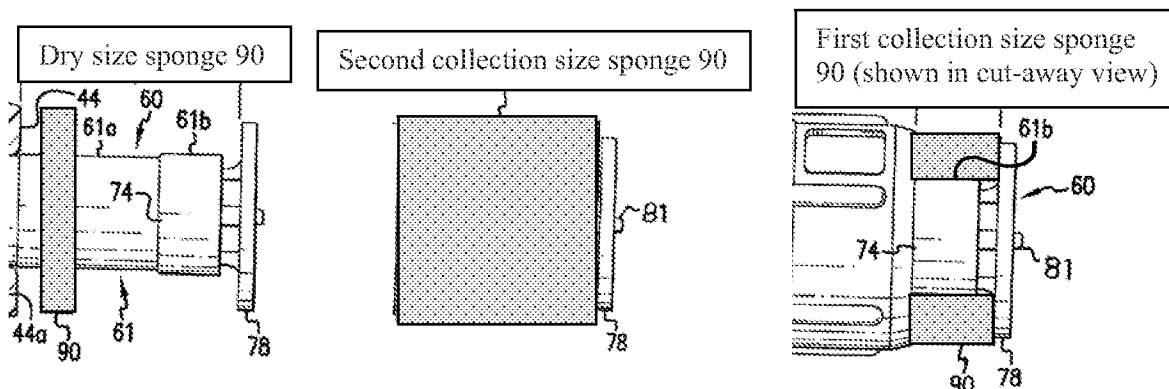
The Office Action sent on November 30, 2009, was received and its contents carefully reviewed. Claims 1, 4, 6, 7, 12-23, 25, 46-52, 73-75, and 77 were originally pending prior to the Office Action of November 30, 2009. Above, Applicants amended claims 1, 6, 7, 12-14, 18, 20, 21, 23, 25, 46-49, 51, 73, 74, and 77 as shown in the listing of claims. Applicants canceled claim 50. Applicants amended the claims to provide additional structural and component descriptions for the features of the claimed invention. Applicants also amended the claims to recite further structural pieces and components of the claimed invention as opposed to characteristics of components or relative references to other structures in the claimed invention. There is ample support for the above amendments in the original disclosure, for example in at least paragraphs [0034-0046], in Figures 1-5, and throughout the original disclosure. Applicants respectfully submit that no new material was added. Claims 1, 4, 6, 7, 12-23, 25, 46-49, 51, 52, 73-75, and 77 remain pending and are believed to be in condition for allowance. Applicants respectfully request reconsideration of this application in light of the following remarks.

#### **A. Claim Rejections under 35 U.S.C. § 102**

Claims 1, 4, 6-7, 9, 12-23, 25, 46-52, and 73-76 stand rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Shah U.S. Patent No. 4,014,322 ("the Shah patent"). In view of the comments below, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

##### **1. The Shah Patent does not Disclose or Suggest all Features of Independent Claim 1**

The present invention is generally directed to a sample collector and a test device. The sample collector and test device can be used to collect and assay fluid samples to detect the presence of analytes in a collected fluid sample. Claim 1 recites a sample collector and test device that employs an expandable sponge with a dry size before a sample is collected, a second collection size after a sample has been collected, and a first collection size that results from expressing a portion of the sample from the sponge when the sponge was its second collection size. Graphically, the sizes may be depicted as follows:



As shown in the listing of claims, independent claim 1 recites the sample collection device for assay that includes a handle portion, a collector portion, and the expandable sponge. The handle portion and collection portion are used with a housing to effect the sponge sizing.

Claim 1 further recites the handle portion has a first end and a second end, and the collector portion has a first end and a second end. Additionally, claim 1 recites that the first end of the collector portion is operably connected to the second end. The first end of the collector portion is detachably coupled to the second end of the handle portion. The second end of the collector portion has a base and is movable relative to the second end of the handle portion when the first end of the collector portion is coupled to the second end of the handle portion. The collector portion has at least an extended size and a contracted size, and the sizes are defined by a configurable distance between the second end of the collector portion and the second end of the handle portion.

Claim 1 recites that the expandable sponge is disposed on the collector portion and has a dry size, a first collection size, and a second collection size as shown above. The first collection size is when the sponge holds a first amount of sample, and the second collection size is when the sponge holds a second amount of sample. As shown above, the first collection size is smaller than the second collection size. A sufficient sample has been collected when the second collection size is substantially equal to the extended size of the collector portion. Further, claim 1 recites that the sponge is disposed between the base and the second end of the handle portion. When the second end of the collector portion is moved

relative to the second end of the handle portion, the collector portion is reconfigured from the extended (second) size to the contracted (first) size, and a sample portion sufficient for assay is discharged from the sponge through the base.

Additionally, claim 1 recites that the collector portion includes a blocking portion configured to engage the second end of the handle portion to define a sample retaining size of the collector portion and to impede movement of the second end of the collector portion relative to the second end of the handle portion, such that movement of the second end of the collector portion to engage the blocking portion with the second end of the handle portion allows the discharge of a first portion of sample for assay from the sponge while placing the sponge in the first collection size and retaining a second portion of sample in the sponge for subsequent assay.

The Shah patent describes a specimen collecting device with a container and a liquid sampling means. The liquid sampling means include compressible liquid absorption means for receiving the liquid specimen and handle means for supporting the absorption means. The device also has means for compressing the absorption means in the container. See col. 1, lines 43-50 of the Shah patent. While the Shah patent discloses that the compressing means releases the specimen from the absorption means into the container chamber, there is no disclosure or suggestion of retaining a second portion of sample in the sponge for subsequent assay as recited in independent claim 1 of the present application. See col. 2, lines 3-5 of the Shah patent.

For example, the Shah patent discloses a sponge 56, but there is no disclosure or suggestion in the Shah patent that the sponge has a dry size, a first collection size, and a second collection size, where sufficient sample is collected when the sponge is in the first collection size and that a second portion of sample in the sponge is retained for subsequent assay when the sponge is compressed to the second collection size as recited in claim 1 of the present application. Also, there is no disclosure or suggestion in the Shah patent of a blocking portion of the collector configured to engage the second end of the handle portion to define a sample retaining size such that movement of the collector portion to the blocking position allows the discharge of a first portion of sample for assay while retaining a second portion of sample in the sponge for subsequent assay.

In the Office Action of November 30, 2009, the Examiner asserted that Figures 1 and 2 of the Shah patent show a sponge 56 with a dry size and that Figures 3-5 disclose sponge 56 engaged between plate 50 and lid 34 to express only a portion of the sample from the sponge 56. However, this is not evident from the Shah patent, and even if it were, there is no disclosure or suggestion that sufficient sample is collected when the sponge is in the first collection size and that a second portion of sample in the sponge is retained for subsequent assay when the sponge is compressed to the second collection size as recited in claim 1 of the present application. Figures 1 and 2 of the Shah patent illustrate the sponge 56 with a dry size when exposed for collecting the specimen. See also col. 3, lines 48-51. As the sponge 56 absorbs a sample, it expands laterally and longitudinally relative to the shaft 40. See col. 3, lines 65-68 and Figure 3.

Figure 4 of the Shah patent illustrates the specimen being released from the sponge. See also col. 4, lines 18-42. The Shah patent describes the manner in which the shaft is moved outwardly through the lid aperture 38 to reduce the spacing between the plate and lid to compress the wetted sponge. The Shah patent further describes that the movement of the shaft stops at an outer position when the specimen has been substantially compressed from the sponge. See col. 4, lines 28-30. The Shah patent describes a dry sponge 56, collecting a sample specimen by wetting the sponge 56 with the specimen, and expressing the specimen into the container chamber 28 by raising the wetted sponge 56 and compressing the sponge 56 between the plate 50 and the lid 34 to release the sample.

There is no mention or suggestion in the Shah patent of the sponge having two collection sizes much less holding sufficient sample for subsequent assay when the sponge is a smaller (first) collection size. See at least page 2, paragraph 2 of the Office Action sent November 30, 2009. In previously making the rejections based on the Shah reference, the Examiner asserted that the Shah patent teaches that “[a]bsorbent/sponge (56) has a first size prior to sample application where it is the width of slot (52) and a second larger size when the sample is applied that is larger than the distance between slot (52) and slot (54).” See page 2 of the Office Action sent October 2, 2007. As outlined above, the sponge described in the Shah reference has a dry size and a wet size. The sponge described in the Shah reference does

not, however, have a first collection size and a second collection size as recited by claim 1 of the present application.

On page 3 of the Office Action sent February 9, 2009, the Examiner asserted that “Shah teaches in column 4, lines 30-34 [that] slot (52) retains the sponge(56) in a compressed configuration and this compressed configuration is what the Office intended by a ‘first size(52).’” Yet in this configuration, the handle 48 in the Shah patent is broken away from the remainder of the shaft 40 at the second slot 54 to permit compact storage of the chamber and sample until the lid is removed and the sample is analyzed. See col. 4, lines 36-42. There is no disclosure or suggestion in the Shah patent of the sponge holding sufficient sample for assay when the sponge is a smaller (first) collection size. In fact, the Shah patent discloses that the sample on the bottom of the container will be poured from the container for analysis. See col. 4, lines 40-42. The Shah reference does not disclose or suggest that the sponge 56 has another collection size other than the one depicted and discussed with reference to FIG. 3 that holds an amount of sample for assay.

As such, the Shah patent fails to disclose or suggest all the features recited in independent claim 1 of the present application. Accordingly, Applicants respectfully submit that claim 1 is allowable over the Shah patent. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 1 under 35 U.S.C. § 102(b).

2. The Shah Patent Does Not Disclose or Suggest All the Features of Independent Claims 46, 73, and 77.

Independent claims 46, 73, and 77 recite similar features as those recited in independent claim 1. For example, each of independent claims 46, 73, and 77 recite a “sponge disposed on the collector portion and having a dry size, a first collection size when the sponge holds a first amount of sample and a second collection size when the sponge holds a second amount of sample.” Independent claim 46 further recites that “the second amount of sample is sufficient for a first assay of sample, and the first amount of sample is sufficient for a second assay of the sample subsequent to the first assay.” Independent claims 73 and 77 each additionally recite “the first amount of sample being sufficient for assay” and “a

sufficient sample is collected for assay when the sponge second collection size is substantially equal to the collector portion extended size.”

As outlined above, independent claim 1 recites a “collector portion first end detachably coupled to the handle portion second end and the collector portion second end . . . being movable relative to the handle portion second end when the collector portion is coupled to the handle portion.” Independent claims 46 and 73 each recite “a collector portion first end being coupled to a handle portion second end and the collector portion second end” “being movable relative to the handle portion second end when the collector portion first end is coupled to the handle portion second end.” Independent claim 77 recites that “the collector portion is an elongate member” and that “the handle portion second end defines an opening sized for slidably receiving the elongated member.”

As discussed previously in the Examiner’s interview, in the previous Office Actions, the Examiner equated outer portion 48 of shaft 40 of the Shah reference with Applicants’ claimed “handle portion.” As further discussed during the interview, with reference in particular to FIG. 3, the Shah reference does not disclose or otherwise suggest that any part of either shaft 40 or the plate 50 is movable relative to the outer portion 48 when the end of shaft 40 at slot 54 is coupled to the outer portion 48. The Shah reference also fails to disclose or otherwise suggest that outer portion 48 or any other portion of shaft 40 defines an opening sized for slidably receiving an elongated member. Instead, the Shah reference discloses the outer portion 48 and the remainder of shaft 40 and plate 50 are fixed relative to each other (see in particular FIG. 3) when the outer portion 48 is coupled with the remainder of shaft 40. For at least these additional reasons, independent claims 1, 46, 73, and 77 are patentably distinguishable from the Shah reference.

Each of independent claims 1, 46, 73, and 77 recites a sponge with a dry size and first and second collection sizes, wherein each of the first and second collection sizes holds respective amounts of sample sufficient for assay. As outlined above with regard to claim 1, the Shah patent fails to disclose or suggest these features recited in the independent claims of the present application.

Accordingly, Applicants respectfully submit that claims 46, 73, and 77 are allowable over the Shah patent for at least the reasons outlined above with regard to claim 1. Applicants

respectfully request reconsideration and withdrawal of the rejection of claims 46, 73, and 77 under 35 U.S.C. § 102(b).

3. The Shah Patent Does Not Disclose or Suggest All the Features of Dependent Claims 4, 6, 7, 9, 12-23, 25, 47-52, and 74-76.

Claims 4, 6, 7, 9, 12-23, 25, 47-52, and 74-76 each ultimately depend upon independent claims 1, 46, and 73, respectively, and thereby include all the limitations of the independent claims while reciting additional features of the present invention. Applicants respectfully traverse the rejection of claims 4, 6, 7, 9, 12-23, 25, 47-52, and 74-76 for similar reasons as outlined above with regard to the rejection of claims 1, 46, and 73 under 35 U.S.C. § 102(b). As discussed above, the Shah patent fails to disclose all the elements and limitations recited in independent claims 1, 46, and 73 of the present application. As such, the Shah patent also fails to disclose all the features and limitations of dependent claims 4, 6, 7, 9, 12-23, 25, 47-52, and 74-76 as well. Accordingly, Applicants respectfully submit that claims 4, 6, 7, 9, 12-23, 25, 47-52, and 74-76 are allowable over the Shah patent, as outlined above. Applicants respectfully request reconsideration and withdrawal of the rejection of claims 4, 6, 7, 9, 12-23, 25, 47-52, and 74-76 under 35 U.S.C. § 102(b).

**B. Claim Rejections under 35 U.S.C. § 103**

Claim 77 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Shah U.S. Patent No. 4,014,322 (“the Shah patent”). In view of the comments below, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

1. The Shah Patent does not Disclose or Suggest all Features of Independent Claim 77

Independent claim 77 recites similar features as those recited in independent claims 1, 46, and 73. For example, each of independent claims 46, 73, and 77 recites a “sponge disposed on the collector portion and having a dry size, a first collection size when the sponge holds a first amount of sample and a second collection size when the sponge holds a second amount of sample.” Independent claim 77 additionally recites “the first amount of sample

being sufficient for assay” and “a sufficient sample is collected for assay when the sponge second collection size is substantially equal to the collector portion extended size.”

Independent claim 77 recites a sponge with a dry size and first and second collection sizes, wherein each of the first and second collection sizes holds respective amounts of sample sufficient for assay. As outlined above with regard to claims 1, 46, and 73, the Shah patent fails to disclose or suggest these features recited in the independent claims of the present application.

Accordingly, Applicants respectfully submit that claim 77 is allowable over the Shah patent for at least the reasons outlined above with regard to claims 1, 46, and 73. Applicants respectfully request reconsideration and withdrawal of the rejection of claim 77 under 35 U.S.C. § 103(a).

#### **C. Conclusion**

In view of the above amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims. If the Examiner finds that any issue remains unresolved, or if any new issue arises that could be resolved through discussions with Applicants’ representative, Applicants invite the Examiner to telephone the undersigned to expedite further prosecution of this application.

Respectfully submitted,

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